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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,766	11/20/2003	Fritz Kirchhofer	33728/US	8384
7590	06/01/2006		EXAMINER	
David E. Bruhn DORSEY & WHITNEY LLP Intellectual Property Department 50 South Sixth Street, Suite 1500 Minneapolis, MN 55402-1498				HUH, BENJAMIN
		ART UNIT	PAPER NUMBER	3767
DATE MAILED: 06/01/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.	10/717,766	
Examiner	KIRCHHOFER, FRITZ	
Benjamin Huh	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1) Responsive to communication(s) filed on 3/3/06.  
2a) This action is FINAL.      2b) This action is non-final.  
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

4) Claim(s) 2 and 4-26 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) Claim(s) \_\_\_\_\_ is/are allowed.  
6) Claim(s) 2, 4-26 is/are rejected.  
7) Claim(s) \_\_\_\_\_ is/are objected to.  
8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9) The specification is objected to by the Examiner.  
10) The drawing(s) filed on 20 November 2003 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

1) Notice of References Cited (PTO-892)  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) Notice of Informal Patent Application (PTO-152)  
6) Other: \_\_\_\_\_.

## DETAILED ACTION

### *Drawings*

The drawings are objected to under 37 CFR 1.83(a) because they fail to show the protective cap 4 in figures 1 & 2 comprising a latching/connecting element as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2, 4, & 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Myerson et al (US Patent No. 3063450). The Myerson reference discloses a cannula system in figures 1-5 comprising a cannula support comprising a thread 38 turning in a first direction, an inner thread, and another thread 32 turning in a second, generally opposite direction, an outer thread; and a protective cap 12 having a thread engageable with said thread turning in said second generally opposite direction, and further comprising an injection device (18,2,4) having a thread 24 engageable with said thread 38 turning in the first direction.

Claims 9-13 & 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Hollister (US Patent No. 6334857B1). The Hollister reference discloses a cannula support in figure 2 comprising a protective cap 2 wherein at least one latching element, a recess seen in figure 2 with which element 7 cooperates with, is provided on said cannula support and at least one corresponding latching element 7 is provided on said

cap, the latching elements cooperating to create a latching connection between the cannula support and the protective cap 2.

With respect to claim 10, wherein the latching elements, 7 with respect to the recess, can cooperate to form a non-releasable latching connection.

With respect to claim 11, wherein the protective cap can be coupled to the cannula support frictionally without the latching element 7 quite yet at the recess to form the connection.

With respect to claim 12, wherein one of the at least one latching elements on the cannula support and the corresponding latching element on the protective cap is one of the group consisting of a cam, a circumferential ring, an element biased by a spring force, a recess and a through hole, wherein the element is a recess.

With respect to claim 13, wherein the at least one latching element, the recess, is provided on a lateral outer surface of the cannula support, see figure 2.

With respect to claim 18, the reference discloses the method for covering a cannula carried by a cannula support using a cannula protecting cap, wherein the cannula support comprises a latching element 7 and wherein the cannula is temporarily covered when the protecting cap is coupled to the cannula support frictionally without the latching elements quite yet at the recess and permanently covered when the protecting cap is coupled to the latching element as seen in figure 2.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myerson et al (US Patent No. 3063450) as applied to claim 4 and further in view of Hollister (US Patent No. 6334857B1). Now even though Myerson does not explicitly disclose a latching element 7 and at least one complementary latching element, seen as a recess on the cannula support, on one of the inside and outside of said cannula support attention is directed to Hollister. The Hollister reference teaches the use of a protective cap that utilizes latching elements that correspond with a complementary latching element on the outside of a cannula support, see figure 2. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Myerson to incorporate the cap of Myerson in order to provide a latchable protecting means to prevent a user from injury from the needle.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Myerson et al (US Patent No. 3063450) as applied to claim 4 and further in view of Hollister (US Patent No. 6334857B1) as applied in claims 5-6 and further in view of Kobayashi (US Patent No. 6719737B2). Now even though the Myerson in view of Hollister reference does not explicitly disclose a second protective cap arranged with said protective cap

attention is directed to Kobayashi. The Kobayashi reference teaches utilizing a second protective cap which is arranged with a protective cap, see figures 1, 11, & 20. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Myerson in view of Hollister with the teachings of Kobayashi in order to provide a protecting means for before use that can be removed and a permanent protecting means for after use of the needle.

Claims 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hollister (US Patent No. 6334857B1) as applied to claim 9 and further in view of Kobayashi (US Patent No. 6719737B2). Now even though Hollister does not explicitly disclose a second latching element on the cannula support attention is directed to Kobayashi. The Kobayashi reference teaches the use of a circumferential ring 38 in figures 1 & 2, for providing a releasable connection with the cannula support and a cap with a corresponding element. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Hollister with the teachings of Kobayashi in order to provide a releasable connection with the cannula support and the protective cap to possibly reuse the cap or to remove the cap to allow access to narrower locations.

Claims 15-17 & 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollister (US Patent No. 6334857B1) as applied to claim 9 and further in view of Kobayashi (US Patent No. 6719737B2) as applied to claim 14 and further in view of

Myerson et al (US Patent No. 3063450). Now even though Hollister in view of Kobayashi does not disclose a connection element for connecting the cannula support to a pen attention is directed to Myerson. The Myerson reference teaches the use of a cannula support with inner and outer threads wherein the inner threads are a connection element 38 which are fully capable of connecting a cannula support to a pen due to it's size, shape, and ability to work in the environment. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Hollister in view of Kobayashi with the device of Myerson in order to provide a connecting means for a cannula support to a pen.

With respect to claim 16, wherein the connection element creates a connection which requires a lesser force for releasing the connection than the force required for releasing the connection between the at least one latching element on the cannula support and the corresponding latching element on the protective cap.

With respect to claim 17, wherein said protective cap is more easily releasable from said cannula support than the cannula support is from the pen, such as when the cap is placed on the support in a frictional state without the latching elements connected, also wherein it would be obvious to create the cap to be easier to release for improved efficiency for utilizing the device.

With respect to claim 19, see rejections above for Myerson as applied to claim 4 & Hollister as applied to claim 9 and Kobayashi as applied to claim 14 and wherein it would be obvious to one of ordinary skill in the art at the time of the invention to utilize a cam and an inside surface of the inside thread for coupling the support to an injection

device in order to couple the injection device to the cannula support since it is well known in the art to utilize a cam in order to connect an object to a threaded connection.

Claims 20-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myerson et al (US Patent No. 3063450) as applied to claim 4 and further in view of Hollister (US Patent No. 6334857B1) as applied in claim 9 and further in view of Kobayashi (US Patent No. 6719737B2) as applied to claim 14. Now even though the reference do not disclose the first and second portions wherein the second portion having a diameter greater than that of the first portion and wherein the second portion comprises an exterior thread, it would be an obvious design choice to modify the diameters of the respective portions in order to accommodate the sizes of the two items in which they are connecting to, see MPEP 2144.04.

With respect to claims 21-22, see Myerson figure 1 and above rejection for claims 2,4 ,8 by Myerson.

With respect to claims 23, wherein the device is fully capable of performing the connecting and removing of the cap or cannula system to the cannula support or syringe respectively, due to the positioning and directions of the threads (32,38) of Myerson.

#### ***Response to Arguments***

Applicant's arguments with respect to claims 2 & 4-19 have been considered but are moot in view of the new ground(s) of rejection.

**Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sellar (US Patent No. 1050042) & Sessions et al (US Patent No. 4258722) both disclose the use of inner and outer threading cannula supports.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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